

Application No. 09/742,268

Attorney Docket No. 2000P19709

**REMARKS**

Claims 1-15 are pending in this application, with claims 1, 4, 5 and 12 being amended and claim 3 being cancelled by this response. Claims 1 and 12 are amended to further define and clarify the claimed invention. Claim 1 is amended to include the feature of original claim 3. Claims 4 and 5 are formally amended to be dependent on amended Independent Claim 1. Claim 12 is amended to recited "a central expert system including access to a data bank for examining the point of care laboratory measurement data and for assessing sufficiency of said measurement data for preparing a definite diagnosis". Claim 14 is amended to further include the feature added in amended claim 12. Support for the amendments can be found throughout the specification, and specifically on page 3, lines 12-21 and page 5, lines 15-16. Applicant respectfully submits that no new matter has been added by the amendments.

**Rejection of Claims 1-7 and 12-15 under 35 USC § 102(e)**

Claims 1-7 and 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Barnhill et al., (U.S. Patent No. 6,306,087).

The present claimed invention describes a system for the automatic evaluation and quality control of medical point of care laboratory measurement data. The system includes a point of care measuring device disposed at a facility of a physician for obtaining point of care laboratory measurement data. A central expert system is disposed remote from the location of point of care. A data link, selected from the group consisting of a data line and a data network, connects the central expert system to the point of care measuring device. The central expert system is accessible by a treating physician via the data link to function as a virtual laboratory data collection and diagnostic system for acting on the point of care laboratory measurement data to make an evaluation available to the treating physician based on the point of care laboratory measurement data. A central laboratory is connected online to the expert system for automatically reporting back a listing to the treating physician of secondary examinations available for acting on the point of care laboratory measurement data if

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an initial evaluation at the expert system of the point of care laboratory measurement data does not produce a definitive diagnosis.

Barnhill describes a simultaneous multi access reasoning technology system. The system utilizes both existing knowledge and implicit information that can be numerically extracted from training data to provide a method and apparatus for diagnosing and prognosing diseases and for determining the severity and cause of the disease (see Abstract).

However, contrary to the assertion made in the Office Action, Barnhill neither discloses nor suggests "a central laboratory is connected online to said expert system for automatically reporting back a listing to the treating physician of secondary examinations available for acting on said point of care laboratory measurement data if an initial evaluation at said expert system of the point of care laboratory measurement data does not produce a definitive diagnosis" as in the present claimed invention. Rather, the cited passages in Column 13, lines 44-60 of Barnhill describe a two step analysis of the biomarkers specifically to avoid a particular "bias created by a dominant predictive variable when training a network." The users training the network are aware of the variable causing the bias and thus exclude it from the first analysis. Purposefully excluding a specific predictive variable to prevent a bias is not equivalent to "automatically reporting back a listing of secondary examinations available" to run on the point of care data when the initial evaluation "does not produce a definitive diagnosis" as in the present claimed invention. The present claimed invention performs an entirely different and unrelated function than Barnhill. Specifically, when a definitive diagnosis is not readily available from laboratory data which is unclear, or "if the findings cannot be recognized by the expert system...patient specimens are automatically requested at the treating doctor and their further transport to the central laboratory is initiated, and secondary examinations can be specified" by "said central expert system" (Specification, page 3, lines 16-21). Barnhill merely performs an analysis taking a dominant predictive variable into account. Barnhill does not seek to clarify "point of care laboratory measurement data [that] does not produce a definitive diagnosis" as in the present claimed invention. Thus, Barnhill neither discloses nor

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suggests "a central laboratory is connected online to said expert system for automatically reporting back a listing to the treating physician of secondary examinations available for acting on said point of care laboratory measurement data if an initial evaluation at said expert system of the point of care laboratory measurement data does not produce a definitive diagnosis" as in the present claimed invention.

Additionally, Barnhill is concerned with training a neural network to provide output values representing diagnostic values which indicate whether the patient has the disease or may develop the disease. Thus, Barnhill provides no common problem recognition with the present claimed invention. In fact, Barnhill is concerned with a completely different problem than the problem addressed by the present claimed invention. Barnhill, unlike the present claimed invention, is concerned with identifying variables that can be used as accurate predictive indicators of the existence of a disease and training a system to use the identified variables to be predictive of the disease. This is NOT "automatically reporting back a listing to said treating physician of secondary examinations available" for use on the "point of care laboratory measurement data" when there is no "definitive diagnosis" from the initial evaluation by the expert system as in the present claimed invention. Barnhill, in the section cited in the Office Action or elsewhere, provides no 35 USC 112 compliant enabling disclosure or reason or motivation to include "a central laboratory is connected online to said expert system for automatically reporting back a listing to the treating physician of secondary examinations available for acting on said point of care laboratory measurement data if an initial evaluation at said expert system of the point of care laboratory measurement data does not produce a definitive diagnosis" as in the present claimed invention. Therefore, Applicant respectfully submits that amended claim 1 is not anticipated by Barnhill. Consequently, Applicant respectfully requests the rejection of claim 1 be withdrawn.

Claims 2 and 4 - 7 are dependent on claim 1 and are considered patentable for the reasons presented above with respect to amended independent claim 1. Therefore, Applicant respectfully submits that claims 2 and 4 - 7 are similarly not anticipated by

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Barnhill. Consequently, Applicant respectfully requests the rejection of claims 2 and 4  
- 7 be withdrawn.

With respect to amended claim 12, the present claimed invention describes a networked expert system for automatic evaluation and quality control of medical point of care laboratory measurement data. A communication interface receives a message including point of care laboratory measurement data. A central expert system includes access to a data bank for examining the point of care laboratory measurement data and for assessing sufficiency of said point of care laboratory measurement data for preparing a definite diagnosis. A data bank contains up-to-date medical knowledge and patient data. An input processor receives data comprising a diagnostic evaluation of the point of care laboratory measurement data and therapy concepts and background knowledge. A distribution processor forwards the received diagnostic evaluation data and therapy concepts and background knowledge to a destination system.

Contrary to the assertion in the Office Action, Barnhill neither discloses nor suggests "a central expert system including access to a data bank for examining the point of care laboratory measurement data and for assessing sufficiency of said point of care laboratory measurement data for preparing a definite diagnosis" as in the present claimed invention. Rather, the cited passages in Column 7, lines 62-66 of Barnhill recites "an apparatus and process for rapidly diagnosing, screening or prognosing diseases in large numbers of patients, wherein the patient data is transmitted to a central facility from a remote location." Diagnosing and prognosing diseases, as in Barnhill, is not akin to "assessing sufficiency" of a measured result to prepare a definite diagnosis as in the present claimed invention, as suggested by the Office Action. In the present claimed invention, measured data is obtained from a patient at a point of care. This measured data is then assessed to determine if the data is sufficient for providing a definitive diagnosis. Barnhill merely provides a diagnosis and a prognosis of a disease in large numbers of patients. This is unlike the present claimed invention which is a system "for examining the point of care laboratory measurement data and for assessing sufficiency of said point of care laboratory measurement data for preparing a definite diagnosis" as in the present claimed invention.

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Additionally, as discussed above, Barnhill is concerned with training a neural network to provide output values representing diagnostic values which indicate whether the patient has the disease or may develop the disease. This is a completely different problem than that addressed by the present claimed invention, which is primarily concerned with evaluating point of care data received from a patient to ensure it is sufficient to provide a definitive diagnosis. Barnhill has no reason to provide the claimed feature of claim 12. Barnhill describes an improved manner of training an expert system to be predictive. This is wholly unrelated to the present claimed invention which "examines" and "assesses the sufficiency" of data "for preparing a definitive diagnosis". Thus, there is no common problem recognition by Barnhill of the objectives of the present claimed invention. Therefore, Applicant respectfully submits that amended claim 12 is not anticipated by Barnhill. Consequently, Applicant respectfully requests the rejection of claim 12 be withdrawn.

Applicant respectfully submits that claim 14 is also not anticipated by Barnhill. Specifically, as discussed above with respect to claim 1, Barnhill neither discloses nor suggests "said expert system is connected online to a central laboratory for automatically reporting back a listing to the destination system of secondary examinations available for acting on said point of care laboratory measurement data upon at least one of a negative sufficiency assessment and if an initial evaluation at said central expert system of said point of care laboratory measurement data does not produce a definitive diagnosis" as in the present claimed invention. As discussed above with respect to claim 1, the cited passages in Column 13, lines 44-60 of Barnhill describe a two step analysis of the biomarkers specifically to avoid a particular "bias created by a dominant predictive variable when training a network." The users training the network are aware of the variable causing the bias and thus exclude it from the first analysis. Purposefully excluding a specific predictive variable to prevent a bias is not equivalent to "automatically reporting back a listing of secondary examinations available" to act on the point of care data "upon at least one of a negative sufficiency assessment and if an initial evaluation at said central expert system of said point of care laboratory measurement data does not produce a definitive diagnosis" as in the present

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claimed invention. The present claimed invention performs an entirely different and  
unrelated function than Barnhill and therefore is not anticipated by Barnhill.

Claims 13 and 15 are dependent on claim 12 and are considered patentable for  
the reasons presented above with respect to amended independent claim 12. Therefore,  
Applicant respectfully submits that claims 13 and 15 are similarly not anticipated by  
Barnhill. Consequently, Applicant respectfully requests the rejection of claims 13 and  
15 be withdrawn.

In view of the above remarks, it is respectfully submitted that there is no 35  
USC 112 enabling disclosure in Barnhill that anticipates the present claimed invention.  
Thus, in view of the above remarks, it is respectfully submitted that claims 1 and 12 are  
not anticipated by Barnhill. As claims 2, 4, 5, 6 and 7 are dependent on claim 1 and  
claims 13, 14 and 15 are dependent on claim 12, it is respectfully submitted that these  
claims are also not anticipated by Barnhill. It is thus further respectfully submitted that  
this rejection is satisfied and should be withdrawn.

**Rejection of Claims 8 and 9 under 35 USC § 103(a)**

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over  
Barnhill et al., (U.S. Patent No. 6,306,087) in view of Jachimowicz et al., (U.S. Patent  
No. 5,763,862).

Jachimowicz describes a dual card smart card reader including a portable  
housing with a viewing aperture and a virtual image display positioned to provide an  
image at the aperture. Similarly to Barnhill, Jachimowicz neither discloses nor  
suggests "a central laboratory is connected online to said expert system for  
automatically reporting back a listing to the treating physician of secondary  
examinations available for acting on said point of care laboratory measurement data if  
an initial evaluation at said expert system of the point of care laboratory measurement  
data does not produce a definitive diagnosis" as claimed in independent claim 1 of the  
present invention. Jachimowicz is not concerned with providing a list of secondary

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examinations available to run on the point of care data when the initial evaluation "does not produce a definitive diagnosis" as claimed in claim 1. Rather, Jachimowicz is concerned with viewing information stored on a smart card. Jachimowicz (with Barnhill) does not teach (and provides no 35 USC 112 enabling disclosure of) "a central laboratory is connected online to said expert system for automatically reporting back a listing to the treating physician of secondary examinations available for acting on said point of care laboratory measurement data if an initial evaluation at said expert system of the point of care laboratory measurement data does not produce a definitive diagnosis" as in the present claimed invention.

It is respectfully submitted that there is no reason or motivation to combine Barnhill with Jachimowicz. Barnhill is concerned with training a neural network to provide output values representing diagnostic values which indicate whether the patient has the disease or may develop the disease. Jachimowicz describes a system for securely viewing information on a smart card. Barnhill and Jachimowicz relate to and attempt to resolve entirely different problems. Barnhill deals with diagnosing and prognosing diseases. Jachimowicz, on the other hand, relates to securely viewing information on a smart card. Additionally, there is no recognition of the problem addressed by the present claimed invention, namely, providing a system that provides a list of available second examinations to perform on data when then initial evaluation does not produce a definitive diagnosis.

However, even if there was a reason or motivation to combine these two references, the combination of the system of Barnhill with the system of Jachimowicz as suggested in the Office Action would not produce the present claimed invention. This combination would result in a system that stores diagnosis and prognosis information regarding a patient on a selectively accessible smart card. The combination of Barnhill with Jachimowicz neither discloses nor suggests "a central laboratory is connected online to said expert system for automatically reporting back a listing to the treating physician of secondary examinations available for acting on said point of care laboratory measurement data if an initial evaluation at said expert system

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of the point of care laboratory measurement data does not produce a definitive  
diagnosis" as in the present claimed invention.

In view of the above remarks, and the remarks concerning Independent claim 1, it is respectfully submitted that Barnhill and Jachimowicz when taken alone or in combination provide no 35 USC 112 compliant enabling disclosure showing the features claimed in claim 1. As claims 8-9 are dependent on claim 1, it is respectfully submitted that claims 8-9 are patentable for the same reasons as claim 1 discussed above. It is thus further respectfully submitted that this rejection is satisfied and should be withdrawn.

**Rejection of Claims 10 and 11 under 35 USC § 103(a)**

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnhill et al., (U.S. Patent No. 6,599,481) in view of Stevens et al.

Stevens et al. describe a substrate, in the form of a partitioned label, removably attached to a container that can be linked electronically to the operating stations in a laboratory and/or removed and subsequently attached to a document or another container. Similarly to Barnhill, Stevens neither discloses nor suggests "a central laboratory is connected online to said expert system for automatically reporting back a listing to the treating physician of secondary examinations available for acting on said point of care laboratory measurement data if an initial evaluation at said expert system of the point of care laboratory measurement data does not produce a definitive diagnosis" as claimed in independent claim 1 of the present invention. Stevens is not concerned with providing a list of secondary examinations available to run on the point of care data when the initial evaluation "does not produce a definitive diagnosis" as claimed in claim 1. Stevens is concerned with electronically tracking specimens. Stevens (with Barnhill) does not teach (and provides no 35 USC 112 enabling disclosure of) "a central laboratory is connected online to said expert system for automatically reporting back a listing to the treating physician of secondary



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examinations available for acting on said point of care laboratory measurement data if  
an initial evaluation at said expert system of the point of care laboratory measurement  
data does not produce a definitive diagnosis" as in the present claimed invention.

It is respectfully submitted that there is no reason or motivation to combine  
Barnhill with Stevens. Barnhill is concerned with training a neural network to provide  
output values representing diagnostic values which indicated whether the patient has  
the disease or may develop the disease. Stevens describes a means for providing  
electronic information onto or into substrates that can be placed onto, un-coded or  
embedded with a container prior to the container being used as a specimen collection  
device. Barnhill and Stevens relate to entirely different problems. Barnhill deals with  
diagnosing and prognosing diseases and ways to train an expert system to be more  
predictive to better perform the functions thereof. Stevens, on the other hand, deals  
with electronically tracking specimens.

However, even if there was a reason or motivation to combine these two  
references, the combination of the system disclosed by Barnhill with the apparatus  
disclosed by Stevens as suggested in the Office Action would not result in the present  
claimed invention. This combination would result in a system that electronically tracks  
the diagnosis and treatment of patients. The combination of Barnhill with Stevens  
neither discloses nor suggests "a central laboratory is connected online to said expert  
system for automatically reporting back a listing to the treating physician of secondary  
examinations available for acting on said point of care laboratory measurement data if  
an initial evaluation at said expert system of the point of care laboratory measurement  
data does not produce a definitive diagnosis" as in the present claimed invention.

In view of the above remarks, and the remarks concerning Independent claim 1,  
it is respectfully submitted that Barnhill et al. and Stevens et al. when taken alone or in  
combination, provide no 35 USC 112 compliant enabling disclosure showing the  
features claimed in claim 1. As claims 10-11 are dependent on claim 1, it is  
respectfully submitted that claims 10-11 are patentable for the same reasons as claim 1

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discussed above. It is thus further respectfully submitted that this rejection is satisfied  
and should be withdrawn.

Having fully addressed the Examiner's rejections, it is believed that, in view of  
the preceding amendments and remarks, this application stands in condition for  
allowance. Accordingly then, reconsideration and allowance are respectfully solicited.  
If, however, the Examiner is of the opinion that such action cannot be taken, the  
Examiner is invited to contact the applicant's attorney at the phone number below, so  
that a mutually convenient date and time for a telephonic interview may be scheduled.

Respectfully submitted,  
Arne Hengerer et al.

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By:



Alexander J. Burke  
Reg. No. 40,425

Siemens Corporation,  
Customer No. 28524  
Tel. 732 321 3023  
Fax 732 321 3030